

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 21002524	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/SE 2003/000347	International filing date (day/month/year) 04.03.2003	Priority date (day/month/year) 05.03.2002
International Patent Classification (IPC) or national classification and IPC A61K 39/395		
Applicant Orthopaedic Research & Development in Gothenburg AB et al		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 02.10.2003	Date of completion of this report 11.06.2004
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Göran Karlsson/BS Telephone No. +46 8 782 25 00

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/000347

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application

☐ claims Nos. \_\_\_\_\_

because:

☒ the said international application, or the said claims Nos. 25-48  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

A method for treatment of the human or animal body by therapy  
(PCT Rule 67.1 (iv)).

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-24  
are so unclear that no meaningful opinion could be formed (*specify*):

See extra sheet

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the  
Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with  
the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: III

Present claims 1-24 relate to a substance defined by reference to a desirable characteristic or property, namely that inhibits a pro-inflammatory cytokine for treatment of a wound by improving wound healing. The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and / or disclosure within the meaning of Article 5 PCT for only a very limited number of such compound

s. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lacks clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Further, the wording "a substance that inhibits a pro-inflammatory cytokine" and similar expressions in the claims are not clear and concise. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

Consequently, the search has mainly been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely the use of the example compound infliximab for the production of a pharmaceutical composition for treatment of a wound by improving wound healing.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established will not be the subject of an international preliminary examination (Rule 66.1 (e)PCT). This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

A search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely the use of the example compound infliximab for the production of a pharmaceutical composition for treatment of a wound by improving wound healing.

.../...

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: III

Documents cited in the International Search Report:

1) STN International, File ZCAPLUS, accession no. 2002:199887, document no. 136:323691,

Kaser, Arthur et al, "Infliximab in severe steroid-refractory ulcerative colitis: A pilot study", &

Wiener Klinische Wochenschrift (2001), 113(23-24), 930-933

2) STN International, File MEDLINE, accession no. 2000046083, document no. 20046083,

Heller T. et al, "Treatment of severe esophageal Crohn's disease with infliximab", &

INFLAMMATORY BOWEL DISEASES, (1999 Nov) 5 (4) 279-82

3) STN International, File MEDLINE, accession no. 2001011857, document no. 20409486,

Jojic N., "[Pharmacotherapy of inflammatory bowel disease]. "Farmakoterapija inflamatornih bolesti creva", &

ACTA CHIRURGICA JUGOSLAVICA, (2000) 47 (1-2) 51-5

4) STN International, File MEDLINE, accession no. 2001419273, document no. 21360250,

Blam M.E., "Integrating anti-tumor necrosis factor therapy in inflammatory bowel disease: current and future perspectives",

AMERICAN JOURNAL OF GASTROENTEROLOGY, (2001 Jul) 96 (7) 1977-97

5) STN International, File MEDLINE, accession no. 2001553668, document no. 21486185,

Travis S.P. et al, "Treatment of intestinal Behcet's syndrome with chimeric tumour necrosis factor alpha antibody", &

GUT, (2001 Nov) 49 (5) 725-8

Thus, the use of the example compound infliximab for the production of a pharmaceutical composition for treatment of a wound by improving wound healing is known from the cited documents and such a use is therefore lacking novelty.